



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/749,980	12/27/2000	Elaine Lee	8600-0010	6822

7590 09/08/2004

ROBINS AND PASTERNAK LLP
1731 EMBARCADERO ROAD, SUITE 230
PALO ALTO, CA 94303

EXAMINER

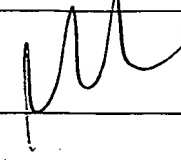
BAXTER, JESSICA R

ART UNIT PAPER NUMBER

3731

DATE MAILED: 09/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/749,980	Applicant(s) LEE, ELAINE	
	Examiner Jessica R Baxter	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 May 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-11,14-16,19,21-24 and 31-37 is/are pending in the application.
- 4a) Of the above claim(s) 3-6,21,22 and 31-37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,7-11,14-16,19,23,24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. The Restriction requirement was made final in the Office Action dated 28 April 2004.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1, 11, 14, 19 and 24 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,231,590 to Slaikeu et al.

Slaikeu discloses a vaso-occlusive composition consisting of a coil and a bioactive material that comprises at least one cytokine selected from the group consisting of PDGF, bFGF, VEGF and TGF-beta (Column 3 line 63-Column 4 line 5). Slaikeu discloses that the vaso-occlusive member is plasma treated (Column 3 lines 30-32).

3. Claims 1, 7, 15, 19 and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,891,192 to Murayama et al.

Murayama discloses a vaso-occlusive coil coated with a thrombus-stabilizing molecule (Column 1 lines 60-62, column 2 line 64 - Column 3 line 8) wherein the vaso-occlusive member is subject to ion-implantation (Column 2 lines 1-3).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1, 7, 8, 9, 10, 23 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,690,666 to Berenstein et al. in view of U.S. Patent No. 4,414,976 to Schwarz et al.

Berenstein discloses a vaso-occlusive coil that is used with a tissue adhesive (Column 3 lines 14-24). Schwarz teaches that tissue adhesive for use in vascular surgery may be made with Factor XIII, plasminogen activator inhibitor or plasmin inhibitor in order to stimulate wound healing (Column 1 lines 37-44). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the device of Berenstein with the tissue adhesive of Schwarz in order to promote healing.

6. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Slaikeu et al. '590 in view of U.S. Patent No. 6,526,979 to Nikolchev et al.

Slaikeu discloses the claimed invention except for the vaso-occlusive member being microtextured. Nikolchev discloses that an occlusive member is microtextured in order to promote tissue ingrowth and enhance the occlusion of the vessel (Column 14 lines 9-37). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the device of Slaikeu with the microtexturing of Nikolchev in order to enhance tissue ingrowth and occlude the vessel.

Response to Arguments

7. Applicant's arguments filed 20 May 2004 have been fully considered but they are not persuasive.

8. Applicant argues that Slaikou et al. '590 discloses that any bioactive material added to the device must be contained in a collagenous coating. In column 3 line 64-Column 4 line 5, it is clear that the bioactive material may be directly applied to the vaso-occlusive member. Therefore, Slaikou meets the "consisting of" language and thus the rejection over Slaikou et al. '590 is proper.

9. Applicant argues that Murayama et al. '192 does not disclose a thrombus stabilizing molecule as defined by the applicant's specification. The specification does not specifically define thrombus stabilizing molecules. The specification states "other molecules that stabilize thrombus formation or inhibit clot lysis (e.g., proteins or functional fragments of proteins, including but not limited to Factor XII, a2-antiplasmin, plasminogen activator inhibitor-1 (PAI-1) or the like)". A thrombus stabilizing molecule is not limited to the ones listed in the applicant's specification. The proteins used by Murayama control the formation or development of a thrombus (Column 1 lines 60-64). The control of the development or formation of the thrombus includes stabilizing the thrombus. The rejection over Murayama et al. '192 is therefore proper.

10. Applicant argues that Berenstein et al. '666 does not disclose a vaso-occlusive member and a bioactive material. Berenstein discloses both a vaso-occlusive member (coil) and a bioactive material (adhesive). There is no language in the claim that requires the vaso-occlusive member to be assembled with the bioactive material prior to implantation. The adhesive does not need to be attached to the coil, as asserted by the applicant. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed

Art Unit: 3731

invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Schwarz et al. '976 teaches a material that is used in wounds to stop bleeding, connect organs or tissues, or stimulate wound healings. Placing this adhesive in an aneurysm to stimulate healing would be an obvious modification of Berenstein et al. since Berenstein discloses that tissue adhesives may be injected into aneurysms (Column 3 lines 14-24). Therefore the rejection over Berenstein et al. '666 in view of Schwarz et al. '976 is proper.

Conclusion

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessica R Baxter whose telephone number is 703-305-4069. The examiner can normally be reached on M-F 8:30AM - 5:00PM.


Art Unit: 3731

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anh Tuan T. Nguyen can be reached on 703-308-2154. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jessica R Baxter
Examiner
Art Unit 3731


jrb


DAVID O. REIP
PRIMARY EXAMINER